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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/978,544	10/16/2001	Avi J. Ashkenazi	GNE.2630P1C13	5195

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EXAMINER

BLANCHARD, DAVID J

ART UNIT	PAPER NUMBER
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1643

DATE MAILED: 10/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/978,544

Applicant(s)

ASHKENAZI ET AL.

Examiner

David J. Blanchard

Art Unit

1643

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 September 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 58-62 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 58-62 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9/9/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-57 and 63 have been cancelled.
Claim 58 has been amended.
2. Claims 58-62 are pending and under examination.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Information Disclosure Statement

4. The information disclosure statement (IDS) submitted on 9/9/05 has been considered by the Examiner. A signed copy of the IDS accompanies this Office Action.

Rejections/Objections Withdrawn

5. The objections to the specification for various formal matters requiring correction are withdrawn in view of the amendments to the specification filed 9/9/05.
6. The rejection of claims 58 and 63 under 35 U.S.C. 101 as being drawn to non-statutory subject matter as lacking the hand of man is withdrawn in view of the amendments to the claims.
7. The rejection of claims 58 and 63 under 35 U.S.C 112, second paragraph, as the being indefinite in the recitation of "binds" and "specifically binds" is withdrawn in view of the amendments to the claims.
8. The rejection of claim 63 under 35 U.S.C 102(b) as being anticipated by Struyk et al is withdrawn in view of the cancellation of the claim.

9. The rejection of claim 63 under 35 U.S.C 103(a) as being unpatentable over Struyk et al in view of De Boer is withdrawn in view of the cancellation of the claim.

Response to Arguments

10. The rejection of claim 58 under 35 U.S.C 102(b) as being anticipated by Struyk et al is maintained.

It is noted that Applicant's response indicates claims 58-61 as being anticipated by Struyk et al, however, Applicant respectfully reminded that only claims 58 and 63 were rejected as anticipated by Struyk et al (see item no. 10 of the previous Office Action mailed 6/15/05).

The response filed 9/9/2005 has been carefully considered, but is deemed not to be persuasive. The response argues that claim 58 recites an antibody that specifically binds to the polypeptide of SEQ ID NO:523 and "specific binding" refers to an antibody that binds to a particular epitope without binding to another epitope. In response to this argument, applicant has not provided any objective evidence distinguishing the structural and functional characteristics of the presently claimed antibodies over the antibodies taught by Struyk et al. The antibodies taught by Struyk et al bind a polypeptide that is substantially identical, i.e., 97% amino acid identity with the mature polypeptide of SEQ ID NO:523 (lacking the signal sequence; residues 1-28 of SEQ ID NO:523), which is the active form of the protein of the present claims and one of ordinary skill in the art would reasonably conclude that the antibodies of Struyk et al are identical to those claimed. Applicant is reminded that where the claimed and prior art

products are identical or substantially identical in structure or composition, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. In re Best, 562 F.2d at 1255, 195USPQ at 433. (see MPEP 2112.01)

Applicant's arguments appear to suggest that the presently claimed antibodies, which "specifically bind" are specific to epitopes that are unique to the polypeptide of SEQ ID NO:523 and thus, distinguishable from those of the prior art, however, the claims do not require any particular epitope specificity of the claimed antibodies and the two polypeptides share many epitopes that are identical. Thus, absent objective evidence to the contrary, it remains the examiner's position that the antibodies taught by Struyk et al possess the same structural and functional properties as those of the antibodies claimed, i.e., specifically binds the polypeptide of SEQ ID NO:523. The response also argues that the sequence of the claimed polypeptide is substantially divergent from the polypeptide of Struyk et al, particularly at the amino terminal region of SEQ ID NO:523 and antibodies raised to this region would not bind the polypeptide of Struyk et al. In response to this argument, applicant argues with limitations not recited in the rejected claim. Even if claim 58 required the presently claimed antibodies to

specifically bind an epitope in the amino terminal region of SEQ ID NO:523, the amino terminal 28 amino acids are part of the signal peptide, which is cleaved from the protein during processing.

For these reasons the rejection is maintained.

11. The rejection of claims 58-62 under 35 U.S.C. 103(a) as being unpatentable over Struyk et al in view of De Boer et al is maintained.

The response filed 9/9/2005 has been carefully considered, but is deemed not to be persuasive. The response argues as above, Struyk et al does not teach each and every limitation of claims 58-62 because Struyk et al does not teach antibodies that specifically bind to SEQ ID NO:523 and De Boer does not cure the deficiencies of Struyk et al. The examiners arguments above for Struyk et al apply here as well and in view of the teachings of De Boer et al, one of ordinary skill in the art would have been motivated to modify the antibodies of Struyk et al such that the antibodies were monoclonal, humanized, antibody fragments and/or labeled antibodies because De Boer teach that humanized monoclonal antibodies are particularly useful in therapeutics since there is a lower chance of immune reaction when administered for human therapy, fragments are equivalent to full antibodies and labels are useful for visualization. Thus, there would be an advantage to producing these modified antibodies. The strongest rationale for combining references is a recognition, expressly or impliedly in the prior art or drawn from a convincing line of reasoning based on established scientific principles or legal precedent, that some advantage or expected

beneficial result would have been produced by their combination. In re Sernaker, 702 F.2d 989, 994-95, 217USPQ 1, 5-6 (Fed. Cir. 1983) (MPEP 2144). Further, one of ordinary skill in the art would have had a reasonable expectation of success in making the above modifications because such forms of antibodies were routinely made and used in the art at the time of the invention as evidenced by De Boer.

Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

Conclusions

12. No claim is allowed.

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.


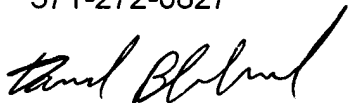
14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Blanchard whose telephone number is (571)

Art Unit: 1643

272-0827. The examiner can normally be reached at Monday through Friday from 8:00 AM to 6:00 PM, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached at (571) 272-0832. The official fax number for the organization where this application or proceeding is assigned is 571-273-8300. Any inquiry of a general nature, matching or filed papers or relating to the status of this application or proceeding should be directed to Tony Parks for Art Unit 1643 whose telephone number is 571-272-0543.

Information regarding the status of an application may be obtained from the patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,
David J. Blanchard
571-272-0827



LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER